Siemens Medical Solutions, Inc. **Ultrasound Division**

SC2000 Ultrasound System 510(k) Submission

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510(k) Summary Prepared July 26, 2013

Sponsor:

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Ultrasound Division

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Submission Date:

July 26, 2013

Device Name:

Acuson SC2000™ Diagnostic Ultrasound System

Common Name:

Diagnostic Ultrasound System

Classification:

Regulatory Class:

11

Review Category:

Tier II

Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550

Product Code 90-IYN

SEP 2 6 2013

Ultrasonic Pulsed Echo Imaging System FR # 892.1560

Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892,1570

Product Code 90-ITX

Diagnostic Intravascular Catheter

FR # 870.1200

Product Code OBJ

A. Legally Marketed Predicate Devices

The Acuson SC2000™ Ultrasound System in this 510k is a modification to SC2000™ Diagnostic Ultrasound System previously cleared in K072365, K102017, K113179, K123622 and K130754.

B. Device Description:

The SC2000™ Diagnostic Ultrasound System is a multi-purpose mobile, software controlled diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode. Color Doppler Mode. Amplitude Doppler Mode. a combination of modes, 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

The SC2000™Ultrasound System has been optimized for user ergonomics with adjustable keyboard height and rotation and independently adjustable Flat Panel Display. There is an available off-line workstation (SC2000WP)

C. Intended Use

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

D. Substantial Equivalence

The submission device is a modification to SC2000™ Diagnostic Ultrasound System previously cleared in K072365, K072786, K102017, K113179, K123622 and K130754 with regard to both intended use and technological characteristics.

interided use and technological characteristics.			l	
Description	Acuson SC2000™ K123622	Acuson \$2000 K111674	Acuson \$2000 K072786	Acuson SC2000™ This submission
System 1998 1998 1999 1999 1999 1999 1999 199				49年19月1日
Hardware Safety – EN60801-1 Certified	x	х	х	x
Software Safety - EN60601-4 Certified	x	X	x	x
Acoustic Thermal Safety - EN60601-2-37 Certified	х	х	x	×
strene directed.				
See Table in Section 4.4.1.4 - All previously cleared	х	Х	х	x
Biocompatibility - Same transducers no new materials	х	Х	х	х
6C1HD Transducer		x		x
AcuNay 8F/10F	x	Х		х
AcuNav V	x	X		x
Soundstar 10F	х	, X		х
Biocompatibility Same transducers no new materials	x	х	x	х
PACCASCONES (C. 1974) A PACCAS	建			
Respirometer	х			x
AcuNav Joystick	x	х		x
	Transition of the second			TO ME THE
SpaceTime™ resolution control	х	X	х	х
Native™ Tissue Harmonic Imaging	X	х	х	x
MultiHertz multiple frequency imaging	х	x	. х	х
RES™ enhanced resolution imaging format	х	X	х	х
Output display standard compliance	x	х .	х	x
Native TEQ™ dynamic ultrasound technology	х	х	х	х
TEQ™ ultrasound technology	x	x	x	x
TEQ™ technology for Spectral PW and CW Doppler	х	х	x	х
Dual screen and live dual imaging	х	X	х	X
Acoustic clip capture	X	×	x	X
eSie Measure Workflow Acceleration	x	x	x	х
Preset functionality with preset ordering and grouping capabilities and linking to MultiHertz TM multiple frequency imaging		v	ļ	
Integrated Street ocho espekiliku	X X	×	X	X
Integrated Stress echo capability	1 .		 	X
Cardiac imaging and quantification package	X	<u> </u>	L	X

DTI™ Doppler tissue imaging includes the following color Doppler capabilities:	×	<u>x :</u>	x	х
DTI Velocity (DTV)	x	х	X	x
Color Doppler Harmonic capability in DTI	х	· X	х	x
High Frame Rate Tissue Doppler (HTD) Capability	x	x	X	X
DTI Energy (DTE)	х	х	Х	х
Color Doppler Velocity (CDV)	х	х	Х	X
Color Harmonic imaging	х	Х	х	X
DTI Pulsed Wave (DTI PW) capability	х	X	X	X
Color Doppler M-Mode for:	х	х	X	х
CDV	х	Х	×	х
OTV	x	х	Х	, x
DTE	х	Х	Х	х
contracting of the second seco				
Cadence™ contrast pulse sequencing technology (CPS)	х	Х	х	x
PrecisonBurst programmable triggering for contrast agent				
destruction	X	X.	X	X
TEQ and NTEQ ultrasound technology for Cadence™ CPS	X	X	X	X
Cardiac Galculations of the control				
Cardiac calculations package	х			Х
Slope Line calculations	x			Х
Generic Calculations/Ratio function	X	and the same than the same tha	Deckerso Period Nation	X
Westlier meging package in Multi-				9419
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF)	x	x	x	X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture	<u> </u>		X X	
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF)	x	_ x		X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE	x x	x x	х	X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology	x x	x x	x	X X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology Advanced Vascular Analysis report package	x x	x x x	x x x	X X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology Advanced Vascular Analysis report package Clarify™ Vascular Enhancement Technology	x x x	x x x x	x x x	X X X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology Advanced Vascular Analysis report package Clarify™ Vascular Enhancement Technology Linear and Vector imaging formats	x x x x	x x x x x	x x x x	X X X X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology Advanced Vascular Analysis report package Clarify™ Vascular Enhancement Technology Linear and Vector imaging formats Auto Doppler option	x x x x	x x x x x	x x x x x	X X X X X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology Advanced Vascular Analysis report package Clarify™ Vascular Enhancement Technology Linear and Vector imaging formats Auto Doppler option Time averaged velocity (TAV) calculation	x x x x	x x x x x x x	x x x x x x x	X X X X X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology Advanced Vascular Analysis report package Clarify™ Vascular Enhancement Technology Linear and Vector imaging formats Auto Doppler option Time averaged velocity (TAV) calculation Vascular Calculation package	x x x x x x x	x x x x x x x	x x x x x x x	X X X X X X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology Advanced Vascular Analysis report package Clarify™ Vascular Enhancement Technology Linear and Vector imaging formats Auto Doppler option Time averaged velocity (TAV) calculation Vascular Calculation package Transcranial imaging	x x x x x x x	x x x x x x x	x x x x x x x	X X X X X X X
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE ™ (tissue contrast enhancement) technology Advanced Vascular Analysis report package Clarify™ Vascular Enhancement Technology Linear and Vector imaging formats Auto Doppler option Time averaged velocity (TAV) calculation Vascular Calculation package Transcranial Imaging	x x x x x x x	x x x x x x x x	x x x x x x x	x x x x x x x
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF) Cadence™ CPS Capture Advanced SieClear™ spatial compounding with Dynamic TCE (tissue contrast enhancement) technology Advanced Vascular Analysis report package Clarify™ Vascular Enhancement Technology Linear and Vector imaging formats Auto Doppler option Time averaged velocity (TAV) calculation Vascular Calculation package Transcranial imaging pplication package syngo® Mitral Valve Assessment	X X X X X X	x x x x x x x x	x x x x x x x	x x x x x x x x
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Wireless Network Connectivity	x		ļ	х
DICOM Print Service	x	хх	X	x
DICOM Media Storage Service	x	X	x	<u> </u>
DICOM Structured Reporting	x	x	x	x

Technological Comparison

The new feature, Clarify VE, or Clarify is the same feature used on the S2000 (K072786). Clarify vascular enhancement technology uses power Doppler flow information to enhance B-mode tissue resolution and reduce acoustic clutter throughout the region of interest. Clarify also provides clearer vessel wall definition, improves tissue boundary detection and tissue contrast resolution, while preserving spatial resolution.

Similarities

As can be seen from the comparison table and the device description above, the modified device has substantially equivalent indications for use and technological characteristics as the predicate devices ACUSON S2000 (K111674, 072786) and ACUSON SC2000 (K113179)

Differences

There are no differences for the new transducer (6C1HD) and feature (Clarify VE) from its use in S2000.

Siemens Medical Solutions, Inc. Ultrasound Division SC2000 Ultrasound System 510(k) Submission

E. Performance Data

The SC2000™is designed, verified, and validated according to the company's design control process and has been subjected to extensive safety and performance testing before release. Final testing of the SC2000 included various safety and performance testing designed to ensure the device meets all of its specifications. Safety tests have been performed to ensure the device complies with applicable industry and safety standards including:

The Acuson SC2000™ has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- Safety and EMC Requirements for Medical Equipment
 - IEC 60601-1
 - IEC 60601-1-1
 - IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

F. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the SC2000 systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

September 26, 2013

Siemens Medical Solutions USA, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K132654

Trade/Device Name: Acuson SC2000[™] Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: 11

Product Code: IYN, IYO, ITX and OBJ

Dated: August 21, 2013 Received: September 4, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson SC2000TM Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Numbers

9L4	6C1HD	V5M
4V1c	8V3	CW2
4Z1c	V7M	10V4

AcuNav 8F and 10F Ultrasound Catheter ACUSON AcuNavTM V 10F Ultrasound Catheter SoundStar 10F Ultrasound Catheter If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Director, Division of Radiological Health

Office of In Vitro Diagnostics

and Radiological Health

Michael D. O'Hara for

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K132654

Device Name: SC2000™ Diagnostic Ultrasound System

Indications for Use:

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal Intraoperative, Intraoperative, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system transmits ultrasound energy from either a transthoracic or transesophageal approach in adult and pediatric patients; and from a transthoracic approach in neonatal and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms, legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

	on UseX CFR 801 Subpart D)	AND/OR	Over-The-Counter Use(21 CFR 801 Subpart C)	-
(PLEASE	DO NOT WRITE BE	LOW THIS LINE-CON	TINUE ON ANOTHER PAGE IF NEED	ED)
Mu	Concurrence	of CDRH, Office of In-	Vitro Diagnostics (OIVD)	
Division S Div	Sign-Off -Office of In ision of Radiological	Vitro Diagnostic Devid Health (DRH)	ces	
510(k)	K 132654		Page 1 of 14	

Device Name:

SC2000 Diagnostic Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic				Γ .								
Fetal		P	P	P	P	P	P		P*	P		P
Abdominal	<u> </u>	P	P	P	P	P	P		P*	P		
Intraoperative Abdominal		P	P	P	P	P	P		P *	P	:	
Intraoperative Neurological	-											
Pediatric		P	P	Р	P	P	P		p.	Р	Р	. Р
Small Organ (specify)				-				.=	.,			
Neonatal Cephalic												
Adult Cephalic		P	P	Р	P	P	P		P*	P		
Cardiac		Р	P	P	P	P	P		P*	Р	P	P
Trans-esophageal		P	P	P	Р	P			P*		Р	
Transrectal												
Transvaginal	\vdash						-					·
Transurethral												
Intra-Luminal		Р	P	P	P	P	P		Р*			P
Peripheral Vessel		P	P	Р	P	P	P	Р	P	P		
Laparoscopic	1											
Musculo-skeletal Conventional		P	P	P		P	Р	Р	P*	Р		
Musculo-skeletal Superficial		Р	P	P		P	P	Р	P*	P		
Other (Neonatal Cardiac)		P	P	P	P	P	P		P*	P		
Other (Intra- Cardiac)		P		P	P	P	P		P*			P

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179

Additional Comments: Combinations include: Doppler, B+CWD+Cold 3+CWD+Power Dopple	B+M, B+PWD, B+CWD, B+Co or Doppler, B+Power Doppler, B	olor Doppler, B+M+ Color Doppler, B+PWD+Color +M+Power Doppler, B+PWD+Power Doppler,
	oncurrence of CDRH, Office	E-CONTINUE ON ANOTHER PAGE IF NEEDED) e of In-Vitro Diagnostics (OIVD) Per 21 CFR 801.109)
Division Sign-Off -C	Office of In Vitro Diagnostic	c Devices
510(k)	<u></u>	Page 2 of <u>14</u>

510(k) Number	r(ifk	inow	n):								
Device Name:				9L	4						
Indications for	Use:			Ult	rasoun	d imagin	g or fluid flo	w analys	is of the h	uman body	as follo
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	
Ophthalmic					\··					 	
Fetal				•					<u></u>	1	
Abdominal	-								-	 	
Intraoperative Abdominal											
Intraoperative Neurological							"				
Pediatric .									-		
Small Organ (specify)											
Neonatal Cephalic Adult Cephalic											
Cardiac	}				<u></u>						
Trans-esophageal		<u> </u>	 -	ļ <u> </u>		 				 	
Transrecial	-			\vdash		 				 	
Transvaginal				· · · ·							
Transurethral		ļ									
Intra-Luminal	\vdash										
Peripheral Vessel		P	P	P	·	P	P	P	P*	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P	
Musculo-skeletal Superficial		P	P	P		Р	P	Р	p+	P	
Other (specify)					_		l			<u> </u>	j
N=new indication Additional Con *Combinations i Doppler, B+CW B+CWD+Power	imen nclud 'D+C	ts: le: B∹ olor I	⊦ <u>М, Е</u> Оорр	3+PWD ler, B+I	, B+CV Power D	VD, B+Co	olor Doppler,	B+M+ <u>Co</u>	olor Dopple	r, B+PWD+ wer Dopple	Color r.
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510(k) Number (if known):

Device Name:

6C1HD

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		р	Р	P	Р	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative										
Pediatric		P	P	P	P	P	P		P+	P
Small Organ (specify)		Р	P	P	P	P	P		p*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac	<u> </u>									
Trans-esophageal										
Transrectal	<u>† </u>		-							
Transvaginal	\vdash									
Transurethral		<u> </u>								
Intra-Luminal	1			·						
Peripheral Vessel		Р	P	P	Р	P	Р		P+	P
Laparoscopic	\vdash							i		
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Abdominal Vascular)		P	P	P	P	P	P		p.	Р

N=new indication. P = Previously Cleared in 510(k) K072365, K102017

Additiona	i Co	mm	ents:
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*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+PwD+Power Doppler, B+CWD+Power Do

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Device Name:	:			V5	M		•				
Intended Use:				Ultı	asound	imaging	or fluid flow	analysis of	f the human	body as fo	llows:
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic					 						
Fetal					· · · · · · ·						
Abdominal				<u> </u>					-		
Intraoperative Abdominal											
Intraoperative Neurological						-			-		
Pediatric		P	Р	P	P	P			P*		P
Small Organ (specify)											
Neonatal											
Cephalic Adult Cephalic								-		<u> </u>	
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P		-	Р*		P
Transrectal											
Transvaginal		-									<u> </u>
Transurethral											
Intra-Luminal											
Peripheral Vessel	<u> </u>										
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial		-									
Other (specify)											
N=new indication. Additional Com Combinations in	ment nolud	ts: e: B+	·М, В	+PWD	, B+CW	/D, B+Co	lor Doppler, I	B+M+ Co	lor Doppler		
Doppler, B+CW B+CWD+Power						oppier, B	+M+POWER L	oppier, B	+PWD+Pov	wer Dobbie	<u> </u>
(PLEASE				ence o	f CDR	H, Office	E-CONTINUI e of In-Vitro Per 21 CFR 8	Diagno			EDED)
Division Sign	-Off	-Off	ice c	of In V	—— itro Di	agnosti	c Devices				

Device Name:				4V	1 c					
ntended Use:				Ult	rasoun	d imagin	g or fluid flo	w analys	is of the h	uman bod
Clinical Application	A	В	M	PWD	CWD	Cotor Doppter	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic		-				1				
Fetal		P	P	P	P	Р	P		P *	P
Abdominal				 		f				
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	Р	Р		P+	P
Small Organ (specify)									· · · · · · · · · · · · · · · · · · ·	<u></u>
Neonatal Conhalia									17.2.1	
Cephalic Adult Cephalic		P	P	P	P	P	P		P *	P
Cardiac		P	P	P	P	P	P		Р•	P
Trans-esophageal						<u> </u>				
Transrectal			-							
Transvaginal						l				
Transurethral										
Intra-Luminal				i —		1				
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial									- "	
Other (Neonatal Cardiac)		P	P	P	P	P	P		P.*	P
enew indication. Additional Com Combinations in Doppler, B+CWI CWD+Power	ment nelud D+Co Dopt	is: e: B+ olor [oler,	-M, B Doppl B+C	s+PWD er, B+F larify V	, B+CW ower D E	/D, B+Co	lor Doppler, I	B+M+ Co loppler, B	+PWD+Por	wer Doppl
,				ence o	f CDR	H, Office	e of In-Vitro	Diagno		

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evice Name	:			8V	3					
ntended Use:				Ult	rasoun	d imagin _i	g or fluid flo	w analys	is of the h	ıman boc
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	Р	P		P.	P
Abdominal	<u> </u>	 -	<u> </u>	<u> </u>	···········					
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	Р		P.	P
Small Organ (specify)										
Neonatal				_						
Cephalic Adult Cephalic								<u> </u>		
Cardiac	 	P	P	P		Р	P		P ·	P
Frans-esophageal	-	_	<u> </u>	-		-				
Fransrectal										
ransvaginal	-		-				7	 		
Fransurethral										
ntra-Luminal	-							<u> </u>		
Peripheral Vessel	-			 						
aparoscopic	-									
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	Р	P	Р	P		P *	P
new indication	ımen	ts:							·	
Combinations i	nelud	le: B+	<u>-М, В</u>	S+PWD	B+CW	/D, B+Co	lor Doppler.	B+M+ Co	lor Doppler	B+PWD
+CWD+Power	Dop	pler,	B+C	larify V	E	oppier, is	TIVITI OWEI L	oppier, D	11 WD1101	мет горрі
(DI ECE	DO.	707	WPI	TE BEI	OW TI	IIS I INF	-CONTINUE	ON ANO	THER PAG	GE IF NEI
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510(k)_____

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510(k) Number (if known):

Device Name	:			CV	W 2						
Intended Use:				Ult	rasoun	d imagin	g or fluid flo	ow analys	is of the h	uman body as follo	DWS
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	
Ophthalmic											
Fetal											•
Abdominal							- · · · · · · · · · · · · · · · · · · ·				
Intraoperative Abdominal					·						
Intraoperative Neurological											
Pediatric					þ						
Small Organ (specify)								_			
Neonatal Cephalic											
Adult Cephalic											
Cardiac			 		P						
Trans-esophageal			 								
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel					Р						
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
N=new indication. Additional Com			ly Cle	eared in	510(k)	K072365	, K102017, K	.113179			
			_								
(PLESE	DO I	NOT	WRI	TE BEI	JOW TI	HIS LINE	-CONTINUE	ON ANO	THER PA	GE IF NEEDED)	
		JUII	Juii				Per 21 CFR 8		(O)	/	
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Division Sign	-Off	-Off	ice (of In V	itro Di	agnosti	c Devices				
510(k)	_	• "			-				F	age 8 of <u>14</u>	

Device Name	:			4Z	1c						
ntended Use:				Ult	rasoun	d imaginį	g or fluid flo	w analys	is of the h	ıman body	as fol
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppter	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other Reni Time 3D
Ophthalmic	1								 		30
Fetal		P	Р	P	P	Р			P*	Р	P
Abdominal	1	1			<u> </u>						
Intraoperative Abdominal											
Intraoperative Neurological						-					
Pediatric	<u> </u>	P	Р	P	P	P			P*	P	P
Small Organ (specify) **											
Neonatal Cephalic Adult Cephalic					·						
Cardiac	<u> </u>	P	P	P	P	Р			Pa ,	P	P
Trans-esophageal	ļ	ļ <u>-</u>	ļ r	-	r	F				r	F
Trans-esophagear	ļ	 	<u> </u>								
Transveginal	<u> </u>										
Transurethral		ļ	<u> </u>			·					
Intra-Luminal											-
Peripheral Vessel	-										
Laparoscopic	-		\vdash								
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)	 	 _		<u> </u>							
N=new indication.	p - 0	resia	nielu i	Classad	in 510	L K 0722	65 K 102012	K113170)	l	
Additional Con Combinations	imeni nclud	ts: e: B+	-М, В	+PWD	, B+C\	/D, B+Co	lor Doppler, l	B+M+ Co	lor Doppler	, B+PWD+6	Color
Doppler, B+CW B+CWD+Power						oppler, B	+M+Power D	oppler, B	+PWD+Pov	ver Doppler	·
(PLEASI	DO.	NOT	WRI	TE BE	LOW T	HIS LINE	-CONTINUI	E ON AN	OTHER PA	GE IF NEE	DED)
	į	Con	curre				e of In-Vitro Per 21 CFR 8		stics (OIV	D)	

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510(k)____

51	10((k) 1	Numi	ber ([if]	known)):
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Device Name: AcuNav 8F and 10F Ultrasound Catheter

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization

of other devices in the heart of adult and pediatric patients as follows:

Clinical Application	٨	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal				<u> </u>							
Intraoperative Abdominal			 							 ,	
Intraoperative Neurological	,										·
Pediatric		Р	P	P	þ	P	P		P*		
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic	}										
Cardiac		Р	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal					_						-
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel	ļ				<u>-</u>			-			
Laparoscopic	-				•						
Musculo-skeletal Conventional											
Musculo-skeletal Superficial							,				
Other (Intra- Cardiac)		Р	P	P	P	Р	P P P P P P P P P P P P P P P P P P P		P*	·	

N=new indication. P = Previously Cleared in 510(k) K071234, K093812, K113179

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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510(k) Number (if known)	510(k)	Number ((if known)	ı:
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Device Name:

ACUSON AcuNav™ V 10F Ultrasound Catheter

Intended Use:

Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal			_								
Intraoperative Abdominal				 					·		
Intraoperative Neurological		-									
Pediatric		P	P	P	P,	Р	P		P.		Р
Small Organ (specify) **			\ <u></u>								
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P	i	P*		P
Trans-esophageal			1			i	<u> </u>				
Transrectal	†				<u> </u>			<u> </u>			
Transvaginal		i ·						·	·		
Transurethral	 -				_			· · · · · · · · · · · · · · · · · · ·			
Intra-Luminal		P	Р	P	P	P	Р		P*		P
Peripheral Vessel	T										
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra- Cardiac)		P	P	Р	P	P	Р		P* .		P

N=new indication. P = Previously Cleared in 510(k) K081808, K113179

Legalitha	Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler,

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510(k) Number (if known):

Device Name: SoundStar 10F Ultrasound Catheter

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of

cardiac and great vessel anatomy and physiology as well as visualization

of other devices in the heart:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal								· · · · · · · · · · · · · · · · · · ·		i	
Intraoperative Abdominal				. <u> </u>	-				<u> </u>		
Intraoperative Neurological											
Pediatric											
Small Organ (specify) **				· · · · ·							
Neonatal Cephalic											
Adult Cephalic										,	
Cardiac		Р	P	Р	Р	P	P		P*		1
Trans-esophageal			ĺ								
Transrectal							,				
Transvaginal										***************************************	
Transurethral											
Intra-Luminal		P	P	P	P	P	P	-	P+		
Peripheral Vessel				<u> </u>							
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra- Cardine)		P	P	P	P	Р	P		P*		

N=new indication. P = Previously Cleared in 510(k) K070242, K113179

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

Prescription Use (Per 21 CFR 6	
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ntended Use:				V7	IVI						
Cultural				Ultr	asound	imaging (or fluid flow	analysis of	f the human	body as fo	llows:
Clinical Application	A	В	M	PWD	C:WD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic									•		
Fetal									,		[
Abdominal		P	P	Р	P	Р	Р		P*	P	Р
Intraoperative Abdominal											
ntraoperative Neurological											
Pediatric		Р	P	P	P	Р			P*		P
Small Organ specify)											
Neonatal Carbalia											
Cephalic Adult Cephalic											
Cardiac		···P	P	Р	P	P			P*		P
Frans-esophageal		Р	P	Р	P	P			P*		P
Fransrectal											
Fransvaginal											
Fransurethral											
Intra-Luminal											
Peripheral Vessel										_	
Laparoscopic											
Musculo-skeletal Conventional		:									
Musculo-skeletal Superficial											
Other (specify)								L			
new indication. dditional Com Combinations i	ment nclud	is: e: B+	м, в	+PWD	, B+ <u>CW</u>	/D, B+Co	lor Doppler, l	B+M+ Co	lor Doppler +PWD+Pov	<u>, B+PWD+</u> ver Donnlei	<u>Color</u>
+CWD+Power	Dop	oler,	B+C	arify V	E	- teb. 101. 10					
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510(k) Number (if known):

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Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
phthalmic			 		<u> </u>					
tal	╁	P	P	P	P	P	P		P *	P
odominal		P	P	P	P	P	P		P *	P
traoperative bdominal		P	Р	P	P	Р	P		P *	Р
traoperative eurological		P	P	Р	Р	P	P		P • .	P
diatric	1	P	P	P	P	Р	P		р•	Р
nall Organ pecify)									-	-
onatal phalic										
dult Cephalic										
ırdiac		P	P	Р	P	Р	Р		P *	Р
ans-esophageal										
ansrectal								****		
ansvaginal										
ansurethral										
tra-Luminal					····					
ripheral Vessel										
paroscopic	1									
asculo-skeletal nventional										
usculo-skeletal perficial									-	
her (Neonatal irdiac)		Р	Р	P	Р	P	P		P *	P
	men nelud	/iousl ts: le: B+	y Cle	ared in	510(k) B+CW	K111674 /D, B+Co	lor Doppler, i	B+M+ Co	lor Doppler	, B+PWD
CWD+Power	Dop	oler,	B+C	larify V	E_					
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